FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
ANTIVIRAL DRUGS ADVISORY COMMITTEE MEETING
HILTON WASHINGTON, DC/SILVER SPRING; 8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND
SEPTEMBER 5, 2007

New drug application (NDA) 22-145, raltegravir potassium, integrase inhibitor 400 mg tablets / Merck & Co., Inc., for treatment of HIV-1 infection in combination with other antiretroviral agents in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy.

The Agency is convening this meeting to solicit the committee's comments on the following questions:

1) Do the available data support accelerated approval of raltegravir for the treatment of HIV-1 infection in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy?

   If no, what additional studies are recommended?

2) If yes, what additional studies would you like to see undertaken as post-marketing commitments?

3) The applicant is proposing a Risk Management Plan for raltegravir including a routine pharmacovigilance plan, ongoing clinical trials, a pregnancy registry, and an active surveillance program. The duration of the active surveillance program is at least three years post-launch. Do you find this duration period acceptable?

4) Please discuss the pros and cons of the following potential treatment strategies in future clinical trials used to support drug development, and more specifically, if you would like to see these studies conducted using raltegravir as post-marketing commitments.

   a) Nucleoside-sparing regimens in treatment-naïve patients using either two-drug/two-class or three-drug/three-class regimens
   b) Nucleoside-sparing regimens or three-drug/three class regimens in first treatment failure patients

5) What strategies would help increase study enrollment of women and minorities?